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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,529	05/06/2002	Christopher Elkins	5470-269	.4127
20792	7590	03/23/2005	EXAMINER	
MYERS BIGEL SIBLEY & SAJOVEC			DEVI, SARVAMANGALA J N	
PO BOX 37428			ART UNIT	PAPER NUMBER
RALEIGH, NC 27627			1645	

DATE MAILED: 03/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/030,529	<b>Applicant(s)</b> ELKINS, CHRISTOPHER	
	<b>Examiner</b> S. Devi, Ph.D.	<b>Art Unit</b> 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 November 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-28 ~~is~~ are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Sequence report (1 page)</u> .         |

*jr*

### **Lack of Unity of Invention(s)**

1) Claim 28 has been amended via the amendment filed 01/09/02.

Claims 1-28 are under prosecution.

Claims 24 and 28 are not included in the invention grouping below, since claim 24 is dependent from a non-existent claim 34.

2) The instant application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 C.F.R. 1.499, Applicants are required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 1-5, 8-10, 14-18, 23 and 25, drawn to an isolated polynucleotide of SEQ ID NO: 1, SEQ ID NO: 3, SEQ ID NO: 5, SEQ ID NO: 7, SEQ ID NO: 9, SEQ ID NO: 11, SEQ ID NO: 13, SEQ ID NO: 15 or SEQ ID NO: 17; a polynucleotide that hybridizes thereto; a vector and a cell comprising the same; a vaccine comprising the same; and a method of detecting a polynucleotide encoding DsrA in a biological sample.
- II. Claims 6, 7 and 20-22, drawn to an isolated DsrA protein of SEQ ID NO: 2; SEQ ID NO: 4; SEQ ID NO: 6; SEQ ID NO: 8; SEQ ID NO: 10; SEQ ID NO: 12; SEQ ID NO: 14; SEQ ID NO: 16; and SEQ ID NO: 18 and a vaccine comprising the same.
- III. Claims 11-13, drawn to an antibody that specifically binds to the DsrA protein.
- IV. Claims 19 and 26, drawn to a mutant *H. ducreyi* strain FX517 which does not encode DsrA and a vaccine comprising the same.
- V. Claim 27, drawn to a vaccine comprising an attenuated *H. ducreyi* strain.

3) The inventions listed above as I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons. The special technical feature of the first claimed product of invention I is an isolated polynucleotide that hybridizes to a DNA having the nucleotide sequence of SEQ ID NO: 1 under stringent conditions. However, such a polynucleotide was already known in the art at the time of the instant invention.

For instance, Fleischmann *et al.* (*Science* 269: 496-512, 1995) taught an isolated gene comprising the nucleotide sequence, CGCACCTTTAACGGCTTAATTTAGAACATTTAGAA encoding DsrA, ArgThrPheAsnGlyLeuIleLeuGluHisLeuGlu (see attached sequence alignment report). This prior art nucleotide is expected to hybridize with the instantly recited SEQ ID NO: 1 at least under low stringency conditions. Therefore, the special technical feature of invention I does not define over the prior art.

Inventions II, III, V and VI are drawn to subsequently claimed products: a protein; an antibody; a mutant *H. ducreyi* strain FX517 which does not encode DsrA; and a vaccine comprising an attenuated *H. ducreyi* strain. These products do not share significant common structural elements with each other or with the polynucleotide product of invention I. Proteins are composed of amino acids, whereas polynucleotides are composed of purine and pyrimidine units. The antibody of invention III is a glycoprotein. The mutant *H. ducreyi* strain FX517 does not encode DsrA of invention IV whereas the vaccine of invention V comprises an attenuated *H. ducreyi* strain and encompasses DsrA-expressing strain.

**4)** This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

(A) The polynucleotide species are as follows: SEQ ID NO: 1; SEQ ID NO: 3; SEQ ID NO: 5; SEQ ID NO: 7; SEQ ID NO: 9; SEQ ID NO: 11; SEQ ID NO: 13; SEQ ID NO: 15; and SEQ ID NO: 17. The claims are deemed to correspond to the species listed above in the following manner: claims 1(a), 3, 5, 17, 18 and 24 (SEQ ID NO: 1); and claims 1(b), 4, 17 and 18 (SEQ ID NO: 3; SEQ ID NO: 5; SEQ ID NO: 7; SEQ ID NO: 9; SEQ ID NO: 11; SEQ ID NO: 13; SEQ ID NO: 15; and SEQ ID NO: 17).

(B) The protein species are as follows: SEQ ID NO: 2; SEQ ID NO: 4; SEQ ID NO: 6; SEQ ID NO: 8; SEQ ID NO: 10; SEQ ID NO: 12; SEQ ID NO: 14; SEQ ID NO: 16; and SEQ ID NO: 18. The claims are deemed to correspond to the species listed above in the following manner: claim 7.

The species listed above do not relate to a single general inventive concept under PCT

Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features because the various nucleotide sequence or protein species do not share a significant common structural element.

Each nucleotide or amino acid sequence cited above requires a separate and non-coextensive structural or sequence search.

5) Applicants are required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

6) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Fax number for submission of amendments, responses and/or papers is (571) 273-8300.

7) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

8) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

March, 2005

  
S. DEVI, PH.D.  
PRIMARY EXAMINER

RESULT 5

H64142

hypothetical protein HI0107 - Haemophilus influenzae (strain Rd KW20)

C;Species: Haemophilus influenzae

C;Date: 10-Sep-1999 #sequence\_revision 10-Sep-1999 #text\_change 28-Jul-2000

C;Accession: H64142

R;Fleischmann, R.D.; Adams, M.D.; White, O.; Clayton, R.A.; Kirkness, E.F.; Kerlavage, A.; Gocayne, J.D.; Scott, J.; Shirley, R.; Liu, L.I.; Glodek, A.; Kelley, J.M.; Weidman, J.; D.M.; Brandon, R.C.; Fine, L.D.; Fritchman, J.L.; Fuhrmann, J.L.; Geoghagen, N.S.M. Science 269, 496-512, 1995

A;Authors: Gnehm, C.L.; McDonald, L.A.; Small, K.V.; Fraser, C.M.; Smith, H.O.; Venter,

A;Title: Whole-genome random sequencing and assembly of Haemophilus influenzae Rd.

A;Reference number: A64000; MUID:95350630; PMID:7542800

A;Accession: H64142

A;Status: nucleic acid sequence not shown; translation not shown

A;Molecule type: DNA

A;Residues: 1-403 <TIGR>

A;Cross-references: GB:U32696; GB:L42023; NID:g1573057; PIDN:AAC21785.1; PID:g1573060; T

A;Note: best homolog was a hypothetical protein from Escherichia coli

C;Genetics:

A;Start codon: GTG

C;Superfamily: hypothetical protein HI0107

Alignment Scores:

Pred. No.:	0.000242	Length:	403
Score:	144.00	Matches:	29
Percent Similarity:	81.40%	Conservative:	6
Best Local Similarity:	67.44%	Mismatches:	8
Query Match:	7.22%	Indels:	0
DB:	1	Gaps:	0

US-10-030-529A-1 (1-1168) x H64142 (1-403)

Qy	1165	CGCACCTTTAACGGCTTAATTTTAGAACATTAGAAAAAATTCGATAGAAGGTACCCAA	1106
Db	358	ArgThrPheAsnGlyLeuIleLeuGluHisLeuGluGluIleProAspGluGlyThrIle	377
Qy	1105	TTTAGGCTAAACCACTTAATATTACCGTTTLAGAAGTGGCGGATAATATGGTGAAAAAA	1046
Db	378	CysGluIleAspGlyLeuLeuIleThrIleLeuGluValGlyAspAsnMetIleLysGln	397
Qy	1045	GTGAAAGTA	1037
Db	398	AlaLysVal	400